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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,616	03/10/2004	Richard W. Gross	15060-69	4077
69949 7590 07/30/2007 PATRICK W. RASCHE (15060) ARMSTRONG TEASDALE, LLP ONE METROPOLITAN SQUARE SUITE 2600 SAINT LOUIS, MO 63102-2740				
			EXAMINER MOSS, KERI A	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 07/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,616	Applicant(s) GROSS ET AL.	
	Examiner Keri A. Moss	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

2. Claim **56** is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 56 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims **1-56** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Examples of grammatical and idiomatic errors are listed below; however, this list is not exhaustive of the errors in the claims.

6. It is unclear what applicant is claiming in claim 1. It is unclear what step is involved in the claimed "subjecting the lipid extract to two dimensional (or multidimensional) (or multi-dimensional) electrospray ionization tandem mass spectrometry (ESI/MS/MS) by iterative processing producing the determination of structure and amount." What is the action and what is the result? Perhaps it would be more clear if applicant reworded the phrase to "subjecting...and producing a determination of structure and amount by iterative processing"? What is being processed iteratively? All claims dependent on claim 1 are thus rejected.

7. Claims 1-19 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the algorithm analysis mentioned in the preamble of claim 1.

8. For clarity, applicant is encouraged to start a new line for each additional method step in all claims containing more than one method step.

9. While claim 15 refers to "triglyceride molecular species," claim 16, which depends from 15, refers to "the triacylglyceride molecular species." Which molecular species does applicant intend to refer to?

10. Regarding claims 30, 36, 38, 40, 42, 44, 51, 53 and 54, the phrases "for example" and "i.e." and "e.g." render the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

11. Claims 4, 10, 19-24, 26-27, 29-30, 33, 36, 38, 40, 42, 44, 46, 48 recite the limitation "TG". There is insufficient antecedent basis for this limitation in the claims.

12. Claims 49-54 are independent claims. The phrasing "In an aspect" is non-standard terminology. These claims do not contain the formal preamble language "comprising" or "consisting of." Furthermore, in these claims, it is unclear what steps are involved in the claimed process as there is no action verb denoting a step.

13. As a general grammatical note, the word "which" follows a comma and the word "that" does not.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Han et al. (Proc. Natl. Acad. Sci. USA, 1994) or Brugger et al. (Proc. Natl. Acad. Sci., USA, 1997) in view of Koivusalo et al. (J. Lipid Res., 2001).

Han discloses "electrospray ionization mass spectroscopic analysis of human erythrocyte plasma membrane phospholipids" involving linear regression analysis for correcting different instrumental efficiencies for molecular species.

Bragger teaches "quantitative analysis of biological membrane lipids at the low picomole level by nano-electrospray ionization tandem mass spectrometry", including ESI-MS/MS tandem spectrometry performed directly on extracts. Calibration functions are applied as described on page 2343, right column and Figure 7.

While Han and Bragger do not specifically disclose analysis of triglycerides, triglycerides are closely related to phospholipids of cell membranes. Han and Bragger do not specifically teach applying non-linear regression analysis for determining correlation functions for correcting efficiencies (sensitivities) of different molecular species.

Koivusalo teaches "quantitative determination of phospholipid compositions by ESI-MS: effects of acyl chain length, unsaturation, and lipid concentration on instrument response [species sensitivities, Ex.]" (Title). Koivusalo indicates that linearity of the instrument response can vary depending on the phospholipids acyl chain length, and linear correction function was applied for low total lipid concentrations, and at high total

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keri A. Moss
Examiner
Art Unit 1743

KAM

BRIAN H. GORDON
BRIAN H. GORDON
PRIMARY EXAMINER
NOV 13 2013